## III. REMARKS

United States Serial No. 10/520,239 was filed on July 18, 2005.

Claims 1-15 were cancelled, and claims 16-35 were added, via Preliminary Amendment.

The PTO mailed a Restriction Requirement on February 1, 2007 restricting the claims into two groups (Group I: claims 16-25; Group II: claims 26-35).

Claims 16-25 were withdrawn from examination in view of Applicants' election of claims 26-35.

Claims 26-35 were amended via Applicants' Response filed on July 18, 2007.

The PTO mailed a Final Office Action on April 30, 2008.

Claims 16-25 have been canceled, and claims 36-45 have been added by Applicants' present Response.

Applicants hereby respectfully respond to the Final Office Action and request reconsideration and allowance of claims 26-45.

### Restriction/Election

It was alleged that the claims of Groups I and II do not relate to a single inventive concept under PCT Rule 13.1. The basis of the finality of the Restriction Requirement is that the chemical structure of the Carmona reference allegedly anticipates the structure of pending claim 22.

Applicants respectfully continue to disagree with the Examiner's position regarding the Carmona reference. The ruthenium (II) compound of pending claim 22 is not anticipated by Carmona. As recited in claim 22, $R_{1c}$ and $R_{3c}$ of the ligand are independently phenyl or substituted phenyl. The Carmona reference does not

disclose or suggest this chemical structure. In the chemical structure of Carmona, $R_{1c}$ and $R_{3c}$ of the ligand must be **methyl**. The claimed chemical structure is not anticipated by Carmona and therefore constitutes a special technical feature defining over the art under PCT Rule 13.2. Therefore, the entire basis for the restriction requirement is erroneous.

In the spirit of placing the application in condition for allowance, and without acquiescing to the propriety of the Restriction Requirement, Applicants have canceled withdrawn claims 16-25. These claims have been canceled without prejudice or disclaimer and Applicants' reserve the right to file the same claims in one or more divisional applications.

## 35 U.S.C. § 112

### Second Paragraph

It is still alleged that the use of the indefinite article "a" in claim 26 renders claims 26-35 indefinite. Applicants maintain their traversal of this rejection for the reasons set forth at Pages 19-20 of their Response filed on January 18, 2008. Nevertheless, in the spirit of placing the application in condition for allowance, Applicants have amended the relevant language from claim 26 "bearing a negative charge" to "bearing negative charge", as helpfully suggested by the Examiner. In view of this amendment, Applicants' respectfully request that the rejections of claims 26-35 under 35 U.S.C. § 112, second paragraph, be withdrawn.

### First Paragraph

While being enabled for the treatment of ovarian adenocarcinoma, for the reasons set forth in the Office Actions, it is alleged that claim 26 is not enabled for the treatment of cancer of cancer in general. Applicants again respectfully disagree and submit that the claims are enabled for treatment of a wide variety of cancers.

Regarding enablement rejections, MPEP § 2164.04, quoting *In re Marzocchi*, 439 F.2d 220, 224 (C.C.P.A. 1971), states that

> "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." MPEP at 2100-198.

Applicants respectfully submit that the Office Action dated July 18, 2007, while listing several literature references, does not provide any information which rebuts Applicants' disclosure that the claimed ruthenium (II) compounds may be used to treat tumours of all forms of neoplastic growth including tumours of the lung, liver, blood cells, skin, pancreas, stomach, colon, prostate, uterus, breast, lymph glands, bladder and ovary. See Specification at Page 18, Lines 10-13. In fact, the data provided in the Grever, et al. reference suggests that compounds with anticancer activity have such activity across numerous types of cancers. Therefore, the disclosure of the use of the compounds to treat the above-identified cancers, when taken in light of the test results relating to the ovarian cancer cell line, provide enablement for the full scope of claim 26.

The Specification also includes working examples of successful *in vitro* testing of exemplary ruthenium (II) compounds. With respect to the alleged "limited examples" provided in the Specification, it has been held that claims are not invalidated simply because specification embodiments do not contain examples explicitly covering the full scope of the claim language." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, (Fed. Cir. 2005).

Further, MPEP § 2164.01(b) states that

> [a]s long as the specification discloses at least one method of making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839 . . . (C.C.P.A. 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 . . . (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987).

Further, Applicants respectfully disagree with the Examiner's position that Example No. 2 shows "no apparent activity." The Specification at Page 26 shows the results for the *in vitro* testing of exemplary ruthenium (II) compounds. Preceding the table of results, the Specification discloses that the ruthenium (II) compounds have an IC50 of less than 150 μm, preferably less than 100 μm, and more preferably less than 50 μm. Examples Nos. 1 and 3-6 all fall within this range. The results for Example No. 2 fall within the range of "less than 150 μm" disclosed in the Specification. According to the Federal Food and Drug Administration, the IC50 value represents the concentration of a drug that is required for 50% inhibition *in vitro*. Therefore, the ruthenium (II) compound of Example No. 2 does indeed possess anti-cancer activity as it falls within the broadest disclosed range of less than 150 μm. It simply takes a larger dose of the ruthenium (II) compound of Example No. 2 as compared with the compounds of Example Nos. 1 and 3-6.

Additionally, MPEP § 2164.01 states that "[t]he fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int's Trade Comm'n 1983), *aff'd sub nom., Massachusetts Institute of Technology v. A.B. Forita*, 774 F.2d 1104 . . . (Fed. Cir. 1985)." MPEP at 2100-94. Most cancer researchers hold either a Ph.D., M.D., or a combined M.D./Ph.D. degree and possess years of clinical training in oncology and/or basic

science research. Therefore, there is a high level of skill in the relevant art. The Specification provides ample guidance and support with respect to the chemical structures of the ruthenium (II) compounds, methods of synthesis of the ruthenium (II) compounds, and protocols of testing the compounds sufficient for one of such skill in the art to make, use and test the disclosed compounds on a wide variety of cell lines without undue experimentation. Accordingly, Applicants respectfully submit that the claims are fully enabled for treating cancer in general and should not be limited only to treatment of ovarian cancer.

**Fees**

By this Response, Applicants have added 10 new claims (claims 36-45). Applicants have also canceled 10 previously withdrawn claims (claims 16-25). Accordingly, Applicants submit that no new claims fees are due to the PTO. In the event, however, that an additional fee is applicable to the filing of this document and the required fee is not enclosed, or the fee submitted is insufficient, the Director is hereby authorized to charge any fees for 14084-005US1/RJW/CP6263 that might be required to effect the filing of this document to Account No. 50-3275.

In light of the amendments and remarks set forth above, Applicants respectfully request that the 35 U.S.C. § 112 rejections of claims 26-35 be withdrawn. Applicants also respectfully request the issuance of a formal Notice of Allowability directed to claims 26-45.

Should there be any questions regarding the above amendments or remarks, the undersigned attorney would welcome a telephone call.

Respectfully submitted,

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7-30-08
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